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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,502	07/18/2003	Uwe Marx	Web212T1	3800
7590	01/24/2006			
Horst Kasper 13 Forest Drive Warren, NJ 07059			EXAMINER AFREMOVA, VERA	
			ART UNIT 1651	PAPER NUMBER
DATE MAILED: 01/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,502	MARX ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/09/04; 1/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I (claims 1-10) in the reply filed on 11/28/2005 is acknowledged. The traversal is on the ground(s) that claims belong to the same class and should be examined together and there is no serious burden in searching and examining all groups of claims. This is not found persuasive because different groups of claims are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims would not necessarily anticipate or render obvious the other group(s). Moreover, as to the question of burden of search, classification of subject matter is also an indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Upon applicants' request claim 22 is rejoined with the Group I claims 1-10. However, instant claims 19-21 appear to provide for the use of apparatus that belongs to non-elected invention(s). Moreover, the instant claims 19-21 do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Thus, arguments with respect to claims 19-21 are moot.

Claims 11-21 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups of inventions, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/28/2005.

Claims 1-10 and 22 are under examination in the instant office action.

Claim Objections

Claims 1-22 are objected to because of the following informalities:

Claim 3 does not indicate dependency as intended. Claims 4-6, 9 are objected to under 37 CFR 1.75(c) as being in improper form. See MPEP § 608.01(n).

Appropriate corrections are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 7-10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,857,464 (Weathers et al) (IDS reference).

Claims are directed to a method for cultivation cells at high densities for obtaining the products from these cells wherein the method comprises step of culturing cells in cultivation chamber(s) that semipermeably separated from the supply container; step feeding cells with gas/cell cultivation medium mixtures; step obtaining products. Some claims are further drawn to the cells being plant or mammalian cells. Some claims are further drawn to gas/cell cultivation medium mixtures such as mist with droplets up to 5000 micrometers. Some claims are further drawn to feeding by spray generated by ultrasound.

US 4,857,464 (Weathers et al) teaches a method for cultivation cells and obtaining the products from these cells in a mist cultivation reactor wherein the method comprises step of culturing cells in cultivation chamber(s) that semipermeably separated from the supply container with mesh and/or membrane (devices 301 and 302 on Fig. 4 and devices 14 and 33 on Fig. 5) and step of feeding cells with gas/cell cultivation medium mixtures in a form of mist having droplets up to 5000 micrometres (col. 2, lines 45-50) and generated by ultrasound devices (col. 3, lines 1-10). The cells include plant cells and animal cells including mammalian hydrodomas (table 1; col. 2, line 69; col.5, line 33) that are cultured at high densities or at high yields (col. 5, line 15). The products are dissolved in the feeding mixture and collected below the cultivation chambers. Thus, the cited reference teaches identical steps and structural elements as required by the claimed method. Therefore, the cited reference is considered to anticipate the claimed invention.

2. Claims 1-4, 7, 9, 10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,255,106 (Marx et al).

Claims are directed to a method for cultivation cells at high densities for obtaining the products from these cells wherein the method comprises step of culturing cells in cultivation chamber(s) that semipermeably separated from the supply container, step of feeding cells with gas/cell cultivation medium mixtures, step obtaining product. Some claims are further drawn to the cells being mammalian cells. Some claims are further drawn to the use of semipermeable membrane for separation. Some claims are further drawn to gas/cell cultivation medium mixtures such as bubbles in liquid.

US 6,255,106 (Marx et al) teaches a method for cultivation mammalian cells at high densities for obtaining the products from these cells wherein the method comprises step of culturing cells in cultivation chamber(s) semipermeably separated from the supply container, step of feeding cells with gas/cell cultivation medium mixtures and step obtaining product (Fig. 1; col. 1, lines 56-65; col. 2, lines 28-30 and lines 52). Thus, the cited reference teaches identical steps and structural elements as required by the claimed method. Therefore, the cited reference is considered to anticipate the claimed invention.

3. Claims 1-7, 9, 10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Knazek (Federation Proceedings. 1974. Vol.33, NO. 8, pages 1978-1981).

Claims are directed to a method for cultivation cells at high densities for obtaining the products from these cells wherein the method comprises step of culturing cells in cultivation chamber(s) that semipermeably separated from the supply container, step of feeding cells with gas/cell cultivation medium mixtures, step obtaining product. Some claims are further drawn to the cells being mammalian cells. Some claims are further drawn to the use of semipermeable membrane for separation and to membrane made from polycarbonate. Some claims are further drawn to gas/cell cultivation medium mixtures such as bubbles in liquid.

The reference by Knazek discloses a method for cultivation mammalian cells at high densities for obtaining the secretion products from these cells wherein the method comprises step of culturing cells on polycarbonate capillaries or in cultivation chamber(s) that semipermeably separated from the supply container, step of feeding cells with gas/cell cultivation medium mixtures (fig. 2) and step obtaining secretion products, for example: prolactin (see fig. 2). Thus,

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the cited reference teaches identical steps and structural elements as required by the claimed method. Therefore, the cited reference is considered to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,857,464 (Weathers et al), US 6,255,106 (Marx et al) and Knazek (Federation Proceedings. 1974. Vol.33, NO. 8, pages 1978-1981).

Claims are directed to a method for cultivation cells at high densities for obtaining the products from these cells wherein the method comprises step of culturing cells in cultivation chamber(s) that semipermeably separated from the supply container, step of feeding cells with gas/cell cultivation medium mixtures, step obtaining product. Some claims are further drawn to the cells being plant or mammalian cells. Some claims are further drawn to the use of semipermeable membrane for separation and to membrane made from polycarbonate. Some claims are further drawn to gas/cell cultivation medium mixtures such as bubbles in liquid or in a form of mist having droplets up to 5000 micrometres. Some claims are further drawn to feeding by spray generated by ultrasound.

The cited US 4,857,464 (Weathers et al), US 6,255,106 (Marx et al) and Knazek are relied upon as explained above for the disclosure of culturing cells including plant cells and

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mammalian cells at high densities for obtaining the products from these cells. The semipermeable membranes used for separation of cultivation chambers from supply container in all cited methods and the membrane materials include polycarbonate (Knazek). The feeding of cells is provided by gas/cell cultivation medium mixtures in all cited methods including the use of mist having droplets up to 5000 micrometres (US 4,857,464).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify membrane materials and form of gas/liquid feeding mixtures with a reasonable expectation of success in culturing cells including plant cells and mammalian cells at high densities for obtaining the products from these cells as adequately demonstrated by the cited references. It would be within the purview of ordinary skill in the art to adjust form of gas/liquid feeding mixtures with regard to the cells used for production of desired products and to choose membrane materials that are available and known for culturing cells. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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January 20, 20065

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER